UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,430	10/15/2001	William S. Borneman	GC626-2D1	6652

7590 05/07/2003

Genencor International, Inc.
925 Page Mill Road
Palo Alto, CA 94034-1013

EXAMINER
PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
1652	7

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/981,430	Borneman et al.
Examiner	**Art Unit**
Rebecca Prouty	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *23, 25-30, and 33-39* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *23, 25-30, 33, and 35-39* is/are rejected.

7) ☒ Claim(s) *34* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1-22, 24, 31, and 32 have been canceled. Claims 23, 25-30, and 33-39 are at issue and are present for examination.

Applicants characterization of parent application 08/952,445 as a continuation of grandparent application 08/722,713 in the amendment filed 10/15/01 is objected to as 08/952,445 includes subject matter not found in 08/722,713. As such the relationship of these applications is incorrect and should be corrected to state that 08/952,445 which is a 371 national phase filing of international application PCT/US97/17614 is a continuation-in-part of application 08/722,713.

Claims 35-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35-37 are confusing in the recitation of "The method according to Claim 23" as claim 23 recites an esterase (in product-by-process language) not a method. For purposes of examination it is assumed that applicants intended "The esterase of claim 23". It should be noted that claims to the process recited within the product-by-process language of Claim 23 was previously examined in the parent application and amendment of these claims to clearly recite only the process would lead to a double patenting rejection.

Claims 23, 25-30, 33 and 35-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 23, 25-30, 33 and 35-39 are directed to any esterase encoded by a nucleic acid which will hybridize to any 400 nucleotides long fragment of SEQ ID NO:29 (Claims 23, 25, 26, and 35-37) or comprising SEQ ID NO:26 (Claims 27-30, 38 and 39) or to any *Aspergillus* esterase of about 38 KD (Claim 33). Claims 23, 25-30, 33 and 35-39 are rejected under this section of 35 USC 112 because the claims are directed to a genus of esterases that have not been sufficiently disclosed in the specification. No description has been provided of the common structural and/or functional features of all polypeptides encompassed by the genera of these claims. No information, beyond the characterization of SEQ ID NO:28 has been provided by applicants which would indicate that they had possession of the claimed genus of polypeptides. The specification does not contain any disclosure of the structure and function of all esterases within the scope of the claimed genus. The genera of polypeptides claimed are large

variable genera including peptides which can have a wide variety of functions as the term esterase encompasses as enormous number of distinct enzymatic activities and structures as the structural features recited in Claims 23, 25-30 and 35-39 define only small regions of the structure of the esterase with no showing that these features correlate with esterase activity. Therefore many structurally and functionally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genera which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genera. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 23, 25-30, 33 and 35-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the esterase of SEQ ID NO:28, does not reasonably provide enablement for any esterase encoded by a nucleic acid which will hybridize to any 400 nucleotides long fragment of SEQ

ID NO:29 or comprising SEQ ID NO:26 or for any *Aspergillus* esterase of about 38 KD. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 23, 25-30, 33 and 35-39 are so broad as to encompass any esterase encoded by a nucleic acid which will hybridize to any 400 nucleotides long fragment of SEQ ID NO:29 (Claims 23, 25, 26, and 35-37) or comprising SEQ ID NO:26 (Claims 27-30, 38 and 39) or to any *Aspergillus* esterase of about 38 KD (Claim 33). The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of esterase enzymes broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its

function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of a single esterase.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all esterases encoded by a nucleic acid which will hybridize to any 400 nucleotides long fragment of SEQ ID NO:29 or comprising SEQ ID NO:26 or to any *Aspergillus* esterase of about 38 KD because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting esterase activity; (B) the general tolerance of esterases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying

any esterase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any esterase encoded by a nucleic acid which will hybridize to any 400 nucleotides long fragment of SEQ ID NO:29 or comprising SEQ ID NO:26 or to any *Aspergillus* esterase of about 38 KD. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of esterases having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country,

more than one year prior to the date of application for patent in the United States.

Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by Faulds et al. (1994).

Faulds et al. teach the isolation and purification of an *Aspergillus niger* ferulic acid esterase (FAE-III) with a molecular weight of 36 KD. 36 KD is well within the range of experimental error in molecular weight estimates by SDS-PAGE and thus clearly within "about 38 KD" as recited in Claim 33.

Claims 23 and 35-37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Faulds et al. (1994) as evidenced by de Vries et al. (1997).

Faulds et al. is discussed above. de Vries et al. teach the amino acid sequence and encoding nucleic acid sequence of the ferulic acid esterase isolated by Faulds et al. The amino acid sequence of the FAE-III protein is 95% identical to SEQ ID NO:28 and encoded by a nucleotide sequence which is greater than 90% identical to the corresponding region of SEQ ID NO:29. Thus de Vries evidences that the ferulic acid esterase taught by Faulds et al. is encoded by a nucleic acid that will hybridize to SEQ ID NO:29 under the conditions recited in Claims 23 and 35-37. The use of a 102/103 rejection for the rejection of a product-by-

process claim has been approved by the courts. While Faulds et al. do not specifically disclose the enzyme produced by recombinant production (as recited by the claims), the production of a protein by a particular process does not impart novelty or unobviousness to a protein when the same protein is taught by the prior art. This is particularly true when the properties of the protein are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. Applicant should note that while de Vries is not prior art to the instant application, this reference was cited only to show that the protein of Faulds et al. inherently meets the limitation of the instant claims to an esterase encoded by a nucleic acid which will hybridize to any 400 nucleotides long fragment of SEQ ID NO:29.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Faulds et al. (1994) as evidenced by de Vries et al. (1997) in view of Christov et al. (1993).

Faulds et al. is discussed above.

Christov et al. teach the use of xylan degrading enzymes including ferulic acid esterases for the improvement of animal feed digestibility. (see pages 471-473). Therefore, it would have been obvious to one of ordinary skill in the art to add the ferulic acid esterase of Faulds et al. to an animal feed composition in order to improve the digestibility of the feed as taught by Christov et al.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Faulds et al. (1994) as evidenced by de Vries et al. (1997) in view of Cuperus et al. (WO95/35362).

Faulds et al. is discussed above.

Cuperus et al. teach the use of xylan degrading enzymes including ferulic acid esterases for textile cleaning. Therefore, it would have been obvious to one of ordinary skill in the art to add the ferulic acid esterase of Faulds et al. to a detergent composition and to use said detergent composition for cleaning textiles in order to improve the removal of stains of vegetable origin as taught by Cuperus et al.

Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rebecca Prouty
Primary Examiner
Art Unit 1652